16796 S035 rsp.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NDA 16-796/S-035

Taylor Pharmaceuticals
1222 west Grand Avenue
Decatur, Illinois 62522

Attention: Richard Taylor
Manager of Regulatory Compliance

FEB 18 2000

Dear Mr. Taylor:

Please refer to your supplemental new drug application dated August 27,1999, received August 30, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Inapsine (droperidol) for Injection, 2.5 mg/mL.

This "Changes Being Effected" supplemental new drug application provides for revision of the carton and container labeling for the 2 mL ampoule.

We have completed the review of this supplemental application and it is approved, effective on the date of this letter, with the minor editorial revision listed below.

Only "5mg/2mL" should be bolded.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the submitted draft labeling (immediate container and carton labels submitted August 27, 1999). These revisions are terms of the approval of this application.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 16-796/S-035." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Susmita Samanta, M.D., Regulatory Project Manager, at (301) 827-7410.

Sincerely,

/S/

Cynthia McCormick, M.D.
Director
Division of Anesthetic, Critical Care,
and Addiction Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

APPEARS THIS WAY
ON ORIGINAL

cc:
Archival NDA 16-796
HFD-170/Div. Files
HFD-170/S.Samanta/C.Schumaker
HFD-170/C.McCormick/B.Rappaport
HFD-170/A.D'Sa
HF-2/MedWatch (with labeling)
HFD-002/ORM (with labeling)
HFD-102/ADRA (with labeling)
HFD-40/DDMAC (with labeling)
HFI-20/Press_Office (with labeling)
HFD-400/OPDRA (with labeling)
HFD-613/OGD (with labeling)
HFD-095/DDMS-IMT (with labeling)
HFD-820/DNDC Division Director
DISTRICT OFFICE

2-18-00

Drafted by: SS/February 15, 2000
Initialed by:CS/February 15, 2000
final:SS/February 18, 2000
filename:16796.S35.AP21500.doc

APPROVAL (AP)

APPEARS THIS WAY
ON ORIGINAL

Division of Anesthetic, Critical Care, and Addiction Drug Products

CONSUMER SAFETY OFFICER REVIEW

FEB 16 2000

Application Number: NDA 16-796/S-035

Name of Drug: Inapsine (droperidol) for injection

Sponsor: Taylor Pharmaceuticals

CSO: Susmita Samanta

Material Reviewed

Inapsine label and carton for 2 mL ampoule (S-035), dated August 27, 1999, compared with label and carton (S-019) submitted on June 18, 1984, approved on December 31, 1987.

Submission Date: 8/27/99

Receipt Dates: 8/30/99

Background and Summary Description:

Labeling Supplement (S-035):

SLR-035 was submitted with a request for Special Supplement-Changes Being Effected for the labeling of the 2 mL ampoule. The revision was prompted by the Agency letter of May 11, 1999, requesting the sponsor to increase the prominence of the strength/concentration by changing the labeling to read as follows: "5 mg/2 mL (2.5 mg/mL)".

Status Report

Reviews Completed:

1. Medical Review: 10/4/99, M.Roberts, M.D.(S-035)
2. CSO Review: 02/15/00, Susmita Samanta

CSO Review:

Please note that the sponsor's proposed revisions are indicated by strikeovers and underlined text. The agency's proposed revisions will be bolded.

The Statement of contents has been revised to include the total contents.
The revisions are as follows:

	Previously Approved	Added
1) Label	2.5 mg/mL	5 mg/2 mL (2.5 mg/mL)
2) Carton	2.5 mg/mL	5 mg/2 mL (2.5 mg/mL)

/S/ 2-16-00
Regulatory Project Manager

/S/
Chemistry Reviewer Comment/Concurrence

/S/
Supervisory Comment/Concurrence

APPEARS THIS WAY
ON ORIGINAL

CC:

Original NDA/16-796
HFD-170/ Division File
HFD-170/ A.D'Sa
HFD-170/ S.Samanta
HFD-170/C. Schumaker

TAYLOR
PHARMACEUTICALS
AN AKORN COMPANY

August 27, 1999

Cynthia McCormick, M.D., Director
Division of Anesthetic, Critical Care and
Addiction Drug Products **(HFD-170)**
CDER, FDA
Document Room 9B-23
5600 Fishers Lane
Rockville, MD 20857

NDA NO. 16-796 REF. NO. 035
NDA SUPPL FOR SLR

ORIGINAL

RE: **Special Supplement – Changes Being Effected to NDA 16-796**
INAPSINE® (droperidol) for Injection

Dear Sir/Madam:

In accordance with 21 CFR §314.70 (c) (2) (iii), Taylor Pharmaceuticals hereby submits a Special Supplement – Changes Being Effected to the subject application to provide for the change in the labeling for the 2 mL Ampoule. The revised labeling will be printed during the fourth quarter of this year.

Reference is made to the Agency letter dated May 11, 1999 (**Attachment A**) requesting Taylor Pharmaceuticals to increase the prominence of the strength/concentration by changing the labeling to read as follows: "5 mg/2 mL (2.5 mg/mL)". The letter, dated May 11, 1999, indicates that the Agency has received a number of reports of medication errors which appear to be directly associated with practitioners incorrectly interpreting the dosing information on the container label. Taylor Pharmaceuticals has not received any reports of medication errors associated with the labeling of INAPSINE®.

Pursuant to the request made in the Agency letter of May 11, 1999, Taylor Pharmaceuticals is providing the revised label and carton for the 2 mL Ampoule. Twelve (12) final printed labels and cartons (Review Copy) and three (3) final printed labels and cartons (Archival Copy) are provided in **Attachment B.**

In addition, we are providing a side-by-side comparison of our label and carton with our last approved labeling with all differences annotated and explained (**Attachment C).**

TAYLOR
PHARMACEUTICALS
AN AKORN COMPANY

Agree with planned changes. The changes will help to clarify the concentration of the 2 ml ampoule. 1 of 3 mg/2 ml
/S/ 10/4/99

CENTER FOR DRUG
REC'D
AUG 30 1999
HFD-170
EVALUATION AND RESEARCH

August 27, 1999

Cynthia McCormick, M.D., Director
Division of Anesthetic, Critical Care and
Addiction Drug Products (**HFD-170**)
CDER, FDA
Document Room 9B-23
5600 Fishers Lane
Rockville, MD 20857

NDA NO. 16-796 REF. NO. 35
NDA SUPPL FOR SCR

DUPLICATE

RE: **Special Supplement – Changes Being Effected to NDA 16-796**
INAPSINE® (droperidol) for Injection

Dear Sir/Madam:

In accordance with 21 CFR §314.70 (c) (2) (iii), Taylor Pharmaceuticals hereby submits a Special Supplement – Changes Being Effected to the subject application to provide for the change in the labeling for the 2 mL Ampoule. The revised labeling will be printed during the fourth quarter of this year.

Reference is made to the Agency letter dated May 11, 1999 (**Attachment A**) requesting Taylor Pharmaceuticals to increase the prominence of the strength/concentration by changing the labeling to read as follows: "5 mg/2 mL (2.5 mg/mL)". The letter, dated May 11, 1999, indicates that the Agency has received a number of reports of medication errors which appear to be directly associated with practitioners incorrectly interpreting the dosing information on the container label. Taylor Pharmaceuticals has not received any reports of medication errors associated with the labeling of INAPSINE®.

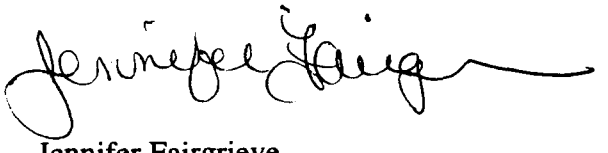
Pursuant to the request made in the Agency letter of May 11, 1999, Taylor Pharmaceuticals is providing the revised label and carton for the 2 mL Ampoule. Twelve (12) final printed labels and cartons (Review Copy) and three (3) final printed labels and cartons (Archival Copy) are provided in **Attachment B.**

In addition, we are providing a side-by-side comparison of our label and carton with our last approved labeling with all differences annotated and explained (**Attachment C).**

150 S. Wyckles Road • P.O. Box 1220 • Decatur, IL 62525-1220 • (217) 428-1100 • FAX (217) 422-9048

Taylor Pharmaceuticals is filing an archival copy (blue folder) and a technical review copy (red folder) of the Supplement. Should you have additional questions, please do not hesitate to contact me at (217) 423-9715 or FAX (217) 423-5206.

Sincerely,



Jennifer Fairgrieve
Associate, Regulatory Affairs

cc: Lou Fraser

APPEARS THIS WAY
ON ORIGINAL

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

APPLICATION TO MARKET A NEW DRUG, BIOLOGIC, OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, 314 & 601)

Form Approved: OMB No. 0910-0338
Expiration Date: April 30, 2000
See OMB Statement on page 2.

FOR FDA USE ONLY

APPLICATION NUMBER

APPLICANT INFORMATION

NAME OF APPLICANT: Taylor Pharmaceuticals (an Akorn Company)	DATE OF SUBMISSION: AUG 27 1999
TELEPHONE NO. *(Include Area Code)*: (217) 423-9715	FACSIMILE (FAX) Number *(Include Area Code)*: (217) 423-5206
APPLICANT ADDRESS *(Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued)*: 1222 West Grand Ave. Decatur, IL 62522	AUTHORIZED U.S. AGENT NAME & ADDRESS *(Number, Street, City, State, ZIP Code, telephone & FAX number)* IF APPLICABLE

PRODUCT DESCRIPTION

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER (If previously issued): NDA 16-796

ESTABLISHED NAME *(e.g., Proper name, USP/USAN name)*: Droperidol	PROPRIETARY NAME *(trade name)* IF ANY: INAPSINE®
CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME *(If any)*: 1-(1-[3-p-fluorobenzoyl) propyl]-1,2,3,6-tetrahydro-4-pyridyl)-2-benzimidazolinone	CODE NAME *(If any)*

DOSAGE FORM: Injectable	STRENGTHS: 2.5 mg/mL	ROUTE OF ADMINISTRATION: IV/IM

(PROPOSED) INDICATION(S) FOR USE: 1) to produce tranquilization and to reduce the incidence of nausea and vomiting in surgical and diagnostic procedures, for premedication, induction and as an adjunct in the maintenance of general and regional anesthesia, and 3) in neuroleptanalgesia in which INAPSINE is given concurrently with an opioid analgesic, such as SUBLIMAZE® (fentanyl citrate) Injection, to aid in producing tranquility and decreasing anxiety and pain.

APPLICATION INFORMATION

APPLICATION TYPE (check one)
☒ NEW DRUG APPLICATION (21 CFR 314.50) ☐ ABBREVIATED APPLICATION (ANDA, AADA, 21 CFR 314.94)
☐ BIOLOGICS LICENSE APPLICATION (21 CFR part 601)

IF AN NDA, IDENTIFY THE APPROPRIATE TYPE ☐ 505 (b) (1) ☐ 505 (b) (2) ☐ 507

IF AN ANDA, OR AADA, IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION
Name of Drug Holder of Approved Application

TYPE OF SUBMISSION (check one)
☐ ORIGINAL APPLICATION ☐ AMENDMENT TO A PENDING APPLICATION ☐ RESUBMISSION
☐ PRESUBMISSION ☐ ANNUAL REPORT ☐ ESTABLISHMENT DESCRIPTION SUPPLEMENT ☐ SUPAC SUPPLEMENT
☐ EFFICACY SUPPLEMENT ☒ LABELING SUPPLEMENT ☐ CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT ☐ OTHER

REASON FOR SUBMISSION: Response to FDA letter dated May 11, 1999.

PROPOSED MARKETING STATUS (check one) ☒ PRESCRIPTION PRODUCT (Rx) ☐ OVER THE COUNTER PRODUCT (OTC)

NUMBER OF VOLUMES SUBMITTED: 1 THIS APPLICATION IS ☒ PAPER ☐ PAPER AND ELECTRONIC ☐ ELECTRONIC

ESTABLISHMENT INFORMATION

Provide locations of all manufacturing, packaging and control sites for drug substance and drug product (continuation sheets may be used if necessary). Include name, address, contact, telephone number, registration number (CFN), DMF number, and manufacturing steps and/or type of testing (e.g. Final dosage form, Stability testing) conducted at the site. Please indicate whether the site is ready for inspection or, if not, when it will be ready.

Cross References (list related License Applications, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, and DMFs referenced in the current application)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

Form Approved: OMB No. *0910-0297*
Expiration Date: *November 30, 1996.*

USER FEE COVER SHEET

See Instructions on Reverse Before Completing This Form.

1. APPLICANT'S NAME AND ADDRESS

Akorn, Inc.
(Taylor Pharmaceuticals)
1222 West Grand Ave.
Decatur, IL 62522

2. USER FEE BILLING NAME, ADDRESS, AND CONTACT

Akorn, Inc.
2500 Millbrook Dr.
Buffalo Grove, IL 60089
Rita McConville

3. TELEPHONE NUMBER *(Include Area Code)*

847-279-6100

4. PRODUCT NAME

INAPSINE (droperidol injection)

DOES THIS APPLICATION CONTAIN CLINICAL DATA? ☐ YES ☒ NO

IF YOUR RESPONSE IS "NO" AND THIS IS FOR A SUPPLEMENT, STOP HERE AND SIGN THIS FORM.

6. USER FEE I.D. NUMBER

7. LICENSE NUMBER/NDA NUMBER

NDA 16-796

8. IS THIS APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCLUSIONS? IF SO, CHECK THE APPLICABLE EXCLUSION.

☐ A LARGE VOLUME PARENTERAL DRUG PRODUCT APPROVED BEFORE 9/1/92

☐ AN INSULIN PRODUCT SUBMITTED UNDER 506

☐ THE APPLICATION IS SUBMITTED UNDER 505(b)(2) *(See reverse before checking box.)*

FOR BIOLOGICAL PRODUCTS ONLY

☐ WHOLE BLOOD OR BLOOD COMPONENT FOR TRANSFUSION

☐ BOVINE BLOOD PRODUCT FOR TOPICAL APPLICATION LICENSED BEFORE 9/1/92

☐ A CRUDE ALLERGENIC EXTRACT PRODUCT

☐ AN "IN VITRO" DIAGNOSTIC BIOLOGIC PRODUCT LICENSED UNDER 351 OF THE PHS ACT

9. a. HAS THIS APPLICATION QUALIFIED FOR A SMALL BUSINESS EXCEPTION? ☐ YES ☐ NO *(See reverse if answered YES)*

b. HAS A WAIVER OF APPLICATION FEE BEEN GRANTED FOR THIS APPLICATION? ☐ YES ☐ NO *(See reverse if answered YES)*

This completed form must be signed and accompany each new drug or biologic product, original or supplement.

SIGNATURE OF AUTHORIZED COMPANY REPRESENTATIVE	TITLE	DATE
Rick Taylor	Manager, Regulatory	September 10, 1999

FORM FDA 3397 (12/93)

FAX

Date 09/10/99

Number of pages including cover sheet 2

TO: Dr. Susmita Samanta

Phone

Fax Phone 1-301-480-8682

FROM: Jennifer Fairgrieve
Taylor Pharmaceuticals
1222 West Grand Ave.
Decatur, IL 62522

Phone 217-423-9715 ext. 154

Fax Phone 217-423-5206

CC: File

REMARKS: ☐ Urgent ☒ For your review ☐ Reply ASAP ☐ Please Comment

RE: User Fee Cover Sheet for Supplement to NDA 16-796

Dr. Samanta,

I inadvertently typed the incorrect address on the letter that attached to the User Fee Cover Sheet for NDA 16-796. Attached is the revised letter. I apologize for any inconvenience this may cause. Please contact me if you have any questions.

Jennifer Fairgrieve
Associate, Regulatory Affairs

TAYLOR
PHARMACEUTICALS
AN AKORN COMPANY

September 10, 1999

Cynthia McCormick, M.D., Director
Division of Anesthetic, Critical Care and
Addiction Drug Products (HFD-170)
CDER, FDA
Document Room 9B-23
5600 Fishers Lane
Rockville, MD 20857

RE: **NDA 16-796**
INAPSINE® (droperidol) for Injection
Special Supplement—Change Being Effected
(Labeling Supplement dated August 27, 1999)

Dear Sir/Madam:

On August 27, 1999, we submitted the above referenced supplement. Enclosed is the User Fee Cover Sheet to be included with the supplement that was inadvertently omitted from the submission.

We apologize for any inconvenience.

Sincerely,

Jennifer Fairgrieve
Associate, Regulatory Affairs

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

Form Approved: OMB No. 0910-0297
Expiration Date: November 30, 1996.

USER FEE COVER SHEET

See Instructions on Reverse Before Completing This Form.

1. APPLICANT'S NAME AND ADDRESS

Akorn, Inc.
(Taylor Pharmaceuticals)
1222 West Grand Ave.
Decatur, IL 62522

2. USER FEE BILLING NAME, ADDRESS, AND CONTACT

Akorn, Inc.
2500 Millbrook Dr.
Buffalo Grove, IL 60089
Rita McConville

3. TELEPHONE NUMBER *(Include Area Code)*
847-279-6100

4. PRODUCT NAME
INAPSINE (droperidol injection)

5. DOES THIS APPLICATION CONTAIN CLINICAL DATA? ☐ YES ☑ NO
IF YOUR RESPONSE IS "NO" AND THIS IS FOR A SUPPLEMENT, STOP HERE AND SIGN THIS FORM.

6. USER FEE I.D. NUMBER

7. LICENSE NUMBER/NDA NUMBER
NDA 16-796

8. IS THIS APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCLUSIONS? IF SO, CHECK THE APPLICABLE EXCLUSION.

☐ A LARGE VOLUME PARENTERAL DRUG PRODUCT APPROVED BEFORE 9/1/92

☐ THE APPLICATION IS SUBMITTED UNDER 505(b)(2) *(See reverse before checking box.)*

☐ AN INSULIN PRODUCT SUBMITTED UNDER 506

FOR BIOLOGICAL PRODUCTS ONLY

☐ WHOLE BLOOD OR BLOOD COMPONENT FOR TRANSFUSION

☐ A CRUDE ALLERGENIC EXTRACT PRODUCT

☐ BOVINE BLOOD PRODUCT FOR TOPICAL APPLICATION LICENSED BEFORE 9/1/92

☐ AN "IN VITRO" DIAGNOSTIC BIOLOGIC PRODUCT LICENSED UNDER 351 OF THE PHS ACT

9. a. HAS THIS APPLICATION QUALIFIED FOR A SMALL BUSINESS EXCEPTION? ☐ YES ☐ NO
(See reverse if answered YES)

b. HAS A WAIVER OF APPLICATION FEE BEEN GRANTED FOR THIS APPLICATION? ☐ YES ☐ NO
(See reverse if answered YES)

This completed form must be signed and accompany each new drug or biologic product, original or supplement.

SIGNATURE OF AUTHORIZED COMPANY REPRESENTATIVE	TITLE	DATE
Rick Taylor	Manager, Regulatory	September 10, 1999

FORM FDA 3397 (12/93)

ATTACHMENT A

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MAY 11 1999

NDA 16-796

Akorn Inc. (Taylor Pharmaceuticals)
1222 West Grand Avenue
Decatur, Illinois 62525

Attention: Richard S. Taylor
Manager, Regulatory Affairs

Dear Mr. Taylor:

Please refer to your New Drug Application (NDA) for INAPSINE (droperidol) for Injection, 2.5mg/mL.

We request that the following change is incorporated in your label, so as to provide information for the safe and effective use of the drug.

We have recently received a number of reports of medication errors which appear to be directly associated with practitioners incorrectly interpreting the dosing information on the container label.

Please make the following changes at your next printing:

> The package labeling (i.e. , vials, inner and outer cartons, etc.)for INAPSINE should be changed to have the most prominent information regarding dosage strength/concentration read as follows: "5mg/2mL (2.5mg/ml)".

We would appreciate your prompt written response so we can complete our review of this matter.

If you have any questions, please contact David Morgan, Regulatory Project Manager, at (301) 872-7410.

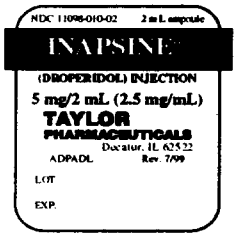
Sincerely,

/S/

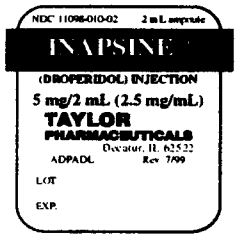
Cynthia G. McCormick, M.D.
Director
Division of Anesthetic, Critical Care,
and Addiction Drug Products, HFD-170
Office of Drug Evaluation III
Center for Drug Evaluation and Research

APPEARS THIS WAY
ON ORIGINAL

ATTACHMENT B



APPEARS THIS WAY
ON ORIGINAL



APPEARS THIS WAY
ON ORIGINAL

INAPSINE®
(DROPERIDOL) INJECTION

10 - 2 mL Ampoules

TAYLOR PHARMACEUTICALS

NDC 11098-010-02

10 - 2 mL Ampoules

INAPSINE®
(DROPERIDOL) INJECTION

TAYLOR PHARMACEUTICALS

5 mg/2 mL (2.5 mg/mL)

FOR INTRAVENOUS OR INTRAMUSCULAR USE

℞ **only** Not to be sold except as an unbroken box.

INAPSINE® 2 mL (DROPERIDOL) INJECTION

ADPADC Rev. 7/99

INAPSINE®
(DROPERIDOL) INJECTION

10 - 2 mL Ampoules

TAYLOR PHARMACEUTICALS

Each mL contains:
Droperidol 2.5 mg. Lactic acid for pH adjustment to 3.4 ± 0.4.

Usual Dosage: For dosage and other information for use, see accompanying product literature.

Store at room temperature, 15°-25°C (59°-77°F). Protect from light.

For your convenience in recording INAPSINE® use

INITIAL/DATE

1 _____
2 _____
3 _____
4 _____
5 _____
6 _____
7 _____
8 _____
9 _____
10 _____

6505-01-104-0399

N 3 11098-010-02 5

TAYLOR PHARMACEUTICALS

07759211

INAPSINE®
(DROPERIDOL) INJECTION

10 - 2 mL Ampoules

TAYLOR PHARMACEUTICALS

NDC 11098-010-02

10 - 2 mL Ampoules

INAPSINE®
(DROPERIDOL) INJECTION

TAYLOR PHARMACEUTICALS

5 mg/2 mL (2.5 mg/mL)

FOR INTRAVENOUS OR INTRAMUSCULAR USE

℞ **only**

Not to be sold except as an unbroken box.

INAPSINE® (DROPERIDOL) INJECTION 2 mL
LOT
EXP.

INAPSINE®
(DROPERIDOL) INJECTION

10 - 2 mL Ampoules

TAYLOR PHARMACEUTICALS

ADPADC Rev. 7/99

Each mL contains:
Droperidol 2.5 mg. Lactic acid for pH adjustment to 3.4 ± 0.4.

Usual Dosage: For dosage and other information for use, see accompanying product literature.

Store at room temperature, 15°-25°C (59°-77°F). Protect from light.

For your convenience in recording INAPSINE® use

INITIAL/DATE

1 _____
2 _____
3 _____
4 _____
5 _____
6 _____
7 _____
8 _____
9 _____
10 _____

6505-01-104-0399

N 3 11098-010-02 5

TAYLOR PHARMACEUTICALS

07759211

ATTACHMENT C

2 mL Label Comparison
INAPSINE® (droperidol) Injection

Section	Proposed Taylor Label	Previous Taylor Label	Reference/Comments
I	NDC 11098-010-02 **2 mL** ampoule	NDC 11098-010-02 **2 mL** ampoule	
II	INAPSINE®	INAPSINE®	
III	**(DROPERIDOL) INJECTION**	**(DROPERIDOL) INJECTION**	
IV	**5 mg/2 mL (2.5 mg/mL)**	**2.5 mg/mL**	Changed per Agency request.
V	{Taylor logo} Decatur, IL 62522	{Taylor logo} Decatur, IL 62522	
VI	ADPADL Rev. 7/99	ADPADL Rev. 7/98	Updated revision date.
VII	LOT EXP.	LOT EXP.	

APPEARS THIS WAY
ON ORIGINAL

2 mL Carton Comparison
INAPSINE® (droperidol) Injection

FRONT PANEL

Section	Proposed Taylor Carton	Previous Taylor Carton	Reference/Comments
I	NDC 11098-010-02 10 - 2 mL Ampoules	NDC 11098-010-02 10 - 2 mL Ampoules	
II	INAPSINE® (DROPERIDOL) INJECTION	INAPSINE® (DROPERIDOL) INJECTION	
III	[Taylor logo]	[Taylor logo]	
IV	**5 mg/2 mL (2.5 mg/mL)**	*See Back Panel, Section I*	Added text to front panel per Agency request.
V	**FOR INTRAMUSCULAR OR INTRAVENOUS USE**	**FOR INTRAMUSCULAR OR INTRAVENOUS USE**	
VI	**℞ only**	**℞ only**	
VII	Not to be sold except as an unbroken box.	Not to be sold except as an unbroken box.	

APPEARS THIS WAY
ON ORIGINAL

2 mL Carton Comparison
INAPSINE® (droperidol) Injection

BACK PANEL

Section	Proposed Taylor Carton	Previous Taylor Carton	Reference/Comments
I	**Each mL contains:** Droperidol 2.5 mg. Lactic acid for pH adjustment to 3.4 ± 0.4.	**Each mL contains:** Droperidol 2.5 mg. Lactic acid for pH adjustment to 3.4 ± 0.4.	
II	**Usual Dosage:** For dosage and other information for use, see accompanying product literature.	**Usual Dosage:** For dosage and other information for use, see accompanying product literature.	
III	Store at room temperature, 15° - 25° C (59° - 77° F). Protect from light.	Store at room temperature, 15° - 25° C (59° - 77° F). Protect from light.	
IV	For your convenience in recording INAPSINE® use INITIAL/DATE 1_____ 2_____ 3_____ 4_____ 5_____ 6_____ 7_____ 8_____ 9_____ 10_____	For your convenience in recording INAPSINE® use INITIAL/DATE 1_____ 2_____ 3_____ 4_____ 5_____ 6_____ 7_____ 8_____ 9_____ 10_____	
V	**6505-01-104-0399**	**6505-01-104-0399**	
VI	[upc code]	[upc code]	
VII	[Taylor logo] Decatur, IL 62522	[Taylor logo] Decatur, IL 62522	

APPEARS THIS WAY
ON ORIGINAL

2 mL Carton Comparison
INAPSINE® (droperidol) Injection

TOP PANEL

Section	Proposed Taylor Carton	Previous Taylor Carton	Reference/Comments
I	INAPSINE® (DROPERIDOL) INJECTION	INAPSINE® (DROPERIDOL) INJECTION	
II	**10 – 2 mL Ampoules**	**10 – 2 mL Ampoules**	
III	[Taylor logo]	[Taylor logo]	

APPEARS THIS WAY
ON ORIGINAL

2 mL Carton Comparison
INAPSINE® (droperidol) Injection

BOTTOM PANEL

Section	Proposed Taylor Carton	Previous Taylor Carton	Reference/Comments
I	INAPSINE® (DROPERIDOL) INJECTION	INAPSINE® (DROPERIDOL) INJECTION	
II	**10 – 2 mL Ampoules**	**10 – 2 mL Ampoules**	
III	[Taylor logo]	[Taylor logo]	

APPEARS THIS WAY
ON ORIGINAL

2 mL Carton Comparison
INAPSINE® (droperidol) Injection

LEFT PANEL

Section	Proposed Taylor Carton	Previous Taylor Carton	Reference/Comments
I	INAPSINE® (DROPERIDOL) INJECTION	INAPSINE® (DROPERIDOL) INJECTION	
II	2 mL	2 mL	
III	LOT EXP.	LOT EXP.	

APPEARS THIS WAY
ON ORIGINAL

2 mL Carton Comparison
INAPSINE® (droperidol) Injection

RIGHT PANEL

Section	Proposed Taylor Carton	Previous Taylor Carton	Reference/Comments
I	INAPSINE® (DROPERIDOL) INJECTION	INAPSINE® (DROPERIDOL) INJECTION	
II	2 mL	2 mL	
III	ADPADC Rev. 7/99	ADPADC Rev. 12/98	Updated revision date.

APPEARS THIS WAY
ON ORIGINAL